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09/622,635	10/12/2000	Olli Kallioniemi	4239-55278	8528

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EXAMINER	
CHAKRABARTI, ARUN K	
ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/622,635	Applicant(s) KALLIONIEMI ET AL.	
	Examiner Arun Chakrabarti	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,10-15,24-29,32-52,87,88,91 and 92* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22,24-52,86-94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action* .

DETAILED ACTION

Specification

1. Claims 1, 9, 12, 14, 16, 23, 25, 43, and 50 have been amended and new claims 86-94 have been added.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> > (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

3. Claims 1, 3, 4, 10-15, 24-29, 32-52, 87, 88 and 91-92 are rejected under 35 U.S.C. 102 (e) as being anticipated by Stapleton et al. (U.S. Patent 6,103,192) (August 15, 2000).

Stapleton et al. teach a method of parallel analysis of tissue specimens (Abstract), the method comprising :

obtaining a plurality of donor specimens (Figure 2 and Column 14, lines 35-36);

placing each donor specimen in an assigned location in a recipient array (Figure 2 and Column 14, lines 55-66);

obtaining a plurality of sections from the recipient array in a manner that each section contains a plurality of donor specimens that maintain their assigned locations (Figure 2 and Examples 4 and 5 and Column 14, lines 55-66);

performing on each section a different biological analysis using the biomarker (Examples 4 and 5);

comparing the results of the different biological analyses in corresponding assigned locations of different sections to determine if there are correlations between the results of the different biological analyses at each assigned locations (Abstract and Examples 4 and 5 and Claim 1).

Stapleton et al. teach a method wherein the biomarker is selected by high-throughput genetic analysis (Abstract, Examples 4 and 5).

Stapleton et al. teach a method wherein the biomarker comprises a numerical alteration of a chromosome, chromosomal region, gene, gene fragment, or a locus (Examples 4 and 5 and 7).

Stapleton et al. teach a method wherein comparing the results comprises determining if there is an alteration of a gene by examining a marker for gene alteration (Examples 4 and 5 and 7).

Stapleton et al. teach a method of analyzing gene amplification for detecting a genomic target sequence that is associated with a specific genetic disorder in a tissue specimen (abstract, Examples 4 and 5 and 7), the method comprising :

screening multiple genes in a biological specimen with a nucleic acid array that detects which genes are abnormally expressed in the biological specimens (Example 5); and

screening multiple tissue specimens in a tissue array with a nucleic acid probe to detect which genes are abnormally expressed in the biological specimens (Example 5);

wherein the result of screening multiple genes is used to select the nucleic acid probe to screen the multiple tissue specimens, or wherein the result of screening multiple tissue specimens is used to select the array that detects which genes are abnormally expressed in the biological specimens (Example 5).

Stapleton et al. inherently teach the donor specimen from a population of tumor cells (Column 8, lines 1-13 and Example 10).

Stapleton et al. teach the different biological analyses are from at least one nucleic acid hybridization. (Example 10).

Stapleton et al. teach the method wherein the donor specimen is from breast cancer. (Column 23, lines 27-60).

Stapleton et al inherently teach the method wherein the characteristics of tumor cells are of patient age, tumor grade and tumor size as he studies the metastatic potential or drug resistance of tumors (Column 23, lines 27-60 and Column 2, lines 19-26).

Stapleton et al inherently teach the method further comprising obtaining the donor specimens from a predetermined morphologically defined region of a tumor and a predetermined cell structure (Column 23, lines 27-34).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-30, 32-52, 87, 88 and 90-94 are rejected under 35 U.S.C. 103 (a) over Stapleton et al. (U.S. Patent 6,103,192) (August 15, 2000) in view of Furmanski et al. (U.S. Patent 4,914,022) (April 3, 1990).

Stapleton et al. teach the method of claims 1, 3, 4, 10-15, 24-29, 32-52, 87, 88 and 91-92 as described above.

Stapleton et al. do not each the method wherein the donor specimen is obtained by boring an elongated sample from the donor specimen which is placed in the assigned location in the recipient array to form an elongated receptacle of the recipient block and obtaining a plurality of copies comprising sectioning the array transverse to the elongated donor specimen.

Furmanski et al teach the method wherein the donor specimen is obtained by boring an elongated sample from the donor specimen which is placed in the assigned location in the recipient array to form an elongated receptacle of the recipient block and obtaining a plurality of copies comprising sectioning the array transverse to the elongated donor specimen. (Figures 1A-F, Column 4, lines 1-6, and claims 1 and 5).

Stapleton et al. do not each the method wherein the diameter of the elongated receptacle is substantially the same as the diameter of the donor specimen.

Furmanski et al teach the method wherein the diameter of the elongated receptacle is substantially the same as the diameter of the donor specimen (Figures 1A-1F).

Stapleton et al. do not each the method wherein the elongated donor sample core is substantially cylindrical core that has a diameter that is less than about 1 mm.

Furmanski et al teach the method wherein the elongated donor sample core is substantially cylindrical core that has a diameter that is less than about 1 mm. (Column 4, lines 17-20).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the method of preparing multiple tissue

samples based on the preparation of elongated sample of Furmanski et al. in the method of Stapleton et al., since Furmanski et al. state, "Advantages of the present invention include greatly enhanced efficiency and speed for tissue testing; greatly decreased cost for multiple tissue testing; great economies in the use of test samples, reagents and test materials such a antibodies; great flexibility and ease of constructing multitissue samples of interest; greatly increased ease in scoring tissue reactivities; ability to combine screening and characterization selection of reagents of interest; ability to select regions of interest for testing from heterogeneous tissue samples (Column 2, lines 45-54)." By employing scientific reasoning, one ordinary artisan would have combined the preparation of elongated sample in the method of parallel analysis of biological specimen of Stapleton et al. to carry out an efficient and economic comparative study of the expression of different oncogenes. An ordinary practitioner would have been motivated to substitute and combine the method of preparing multiple tissue samples based on the preparation of elongated sample of Furmanski et al. in the method of Stapleton et al. in order to achieve the express advantages noted by Furmanski et al. of an invention that include greatly enhanced efficiency and speed for tissue testing; greatly decreased cost for multiple tissue testing; great economies in the use of test samples, reagents and test materials such a antibodies; great flexibility and ease of constructing multitissue samples of interest; greatly increased ease in scoring tissue reactivities; ability to combine screening and characterization selection of reagents of interest; ability to select regions of interest for testing from heterogeneous tissue samples.

6. Claims 1, 3, 4, 10-15, 24-29, 31-52, 87, 88 and 91-92 are rejected under 35 U.S.C. 103 (a) over Stapleton et al. (U.S. Patent 6,103,192) (August 15, 2000) in view of Leveen et al. (Experimental Cell Research, (1993), Vol. 207, pages 283-289).

Stapleton et al. teach the method of claims 1, 3, 4, 10-15, 24-29, 32-52, 87, 88 and 91-92 as described above.

Stapleton et al. do not teach the analyses of PDGFB gene.

Leveen et al teach the analyses of PDGFB gene in cancerous cells (Abstract and Introduction, page 283, column 2, lines 1-14 and Figures 1-7).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the PDGFB oncogene study of Leveen et al. in the method of Stapleton et al., since Leveen et al. state, "Moreover, many human tumor cell types frequently express PDGFA and PDGFB mRNA and protein; rather, structurally normal PDGF genes are frequently found to be constitutively expressed in tumor cells (Page 283, Column 2, lines 5-11)." By employing scientific reasoning, one ordinary artisan would have combined the study of PDGFB oncogene in the method of parallel analysis of biological specimen of Stapleton et al. to carry out a better comparative study of the expression of different oncogenes. An ordinary practitioner would have been motivated to combine the PDGFB oncogene study of Leveen et al. in the method of Stapleton et al., in order to achieve the express advantages noted by Leveen et al. of genes that are frequently found to be constitutively expressed in tumor cells.

7. Claims 1, 3, 4, 10-15, 24-29, 32-52, 86-88 and 91-92 are rejected under 35 U.S.C. 103 (a) over Stapleton et al. (U.S. Patent 6,103,192) (August 15, 2000) in view of Sidransky (U.S. Patent 6,291,163 B1) (September 18, 2001).

Stapleton et al. teach the method of claims 1, 3, 4, 10-15, 24-29, 32-52, 87, 88 and 91-92 as described above.

Stapleton et al. do not each the method wherein the donor specimens are from one or more tumors selected from bladder cancer.

Sidransky teaches the method wherein the donor specimens are from one or more tumors selected from bladder cancer (Column 4, lines 20-38).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the method wherein the donor specimens are from one or more tumors selected from bladder cancer of Sidransky in the method of Stapleton et al., since Sidransky states, "In one embodiment, the method of the invention is useful for the detection of transitional cell carcinoma of the bladder and for the detection of the head and neck cancer (Column 4, lines 35-38)" By employing scientific reasoning, one ordinary artisan would have substituted and combined the method wherein the donor specimens are from one or more tumors selected from bladder cancer of Sidransky in the method of Stapleton et al., to carry out an efficient and economic comparative study of the expression of different oncogenes. An ordinary practitioner would have been motivated to substitute and combine the method wherein the donor specimens are from one or more tumors selected from bladder cancer of Sidransky in

the method of Stapleton et al., in order to achieve the express advantages noted by Sidransky of an invention that is useful for the detection of transitional cell carcinoma of the bladder.

8. Claims 1, 3, 4, 10-15, 24-29, 32-52, 87-89 and 91-92 are rejected under 35 U.S.C. 103 (a) over Stapleton et al. (U.S. Patent 6,103,192) (August 15, 2000) in view of Ertel (U.S. Patent 5,307,262) (April 26, 1994).

Stapleton et al. teach the method of claims 1, 3, 4, 10-15, 24-29, 32-52, 87, 88 and 91-92 as described above.

Stapleton et al. do not each the method wherein the additional information of patient demographics is provided to correlate additional information with the biological analysis.

Ertel teaches the method wherein the additional information of patient demographics is provided to correlate additional information with the biological analysis (Column 29, lines 25-37 and Figures 1-2).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the method wherein the additional information of patient demographics is provided to correlate additional information with the biological analysis of Ertel in the method of Stapleton et al., since Ertel states, "This archival process is unique in that data of many different types are stored together in specific configurations designed to facilitate the generation of a wide variety of useful summary reports (Column 29, lines 25-28)." By employing scientific reasoning, one ordinary artisan would have combined the method wherein the additional information of patient demographics is provided to correlate additional

information with the biological analysis of Ertel in the method of Stapleton et al. to carry out an efficient and economic comparative study of the expression of different oncogenes in a clinical environment. An ordinary practitioner would have been motivated to substitute and combine the method wherein the additional information of patient demographics is provided to correlate additional information with the biological analysis of Ertel in the method of Stapleton et al. in order to achieve the express advantages noted by Ertel of an invention that is unique in that data of many different types are stored together in specific configurations designed to facilitate the generation of a wide variety of useful summary reports.

Response to Amendment

9. In response to amendment, all 112 (second paragraph) and 101 rejections are hereby withdrawn. However, 102 (e) rejection and other 103 rejections are maintained and two new 103 (a) rejections have been included.

Response to Arguments

10. Applicant's arguments filed on April 15, 2002 have been fully considered but they are not persuasive.

Applicant argues that 102 (e) rejection should be withdrawn because Stapleton reference (U.S. Patent 6,103,192) is not entitled to get the priority of the provisional application 60/043,683 (filed on April 14, 1997) as Figure 2 or the description found in column 14, lines 55-66, the Abstract and Claim 1 of the patent is missing in the provisional application. This

argument is not persuasive. Figure 2 of the patent has been clearly described in the provisional application 60/043,683 in Example 3 and the description found in column 14, lines 55-66 on page 12 (first paragraph) respectively. Similarly, Claim 1 and abstract of the patent have been clearly described on page 11 of the provisional application 60/043,683. Therefore, the applicant is hereby notified that 102 (e) rejection is hereby being properly maintained.

Applicant also argues to withdraw 35 U.S.C. 103 (a) rejections. This argument is not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant also argues that there is no motivation to combine the references. This argument is not persuasive, especially in the presence of strong motivation provided by Furmanski et al. since Furmanski et al. state, "Advantages of the present invention include greatly enhanced efficiency and speed for tissue testing; greatly decreased cost for multiple tissue testing; great economies in the use of test samples, reagents and test materials such a antibodies; great flexibility and ease of constructing multitissue samples of interest; greatly increased ease in scoring tissue reactivities; ability to combine screening and characterization selection of reagents of interest; ability to select regions of interest for testing from heterogeneous tissue samples (Column 2, lines 45-54)." Similar logic is applicable to combine other references with Stapleton reference.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237

Arun Chakrabarti,

Patent Examiner,

May 27, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600